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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,586	11/17/2003	Elliot Danforth JR.	49498-C (72015)	4732

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Dike, Bronstein, Roberts & Cushman
Intellectual Property Patent Practice
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209

EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/715,586		DANFORTH ET AL.	
	Examiner		Art Unit	
	Raymond J Henley III		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/25/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

CLAIMS 1-8 AND 16-18 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment filed November 17, 2003 and Information Disclosure Statement filed February 25, 2004 have been received and entered into the application.

Accordingly, claims 9-15 have been canceled and claims 16-18 have been added. Applicants' proposed amendment to the specification appearing at page 3 of the Preliminary Amendment could not be entered because the page/line of the specification where entry is desired has not been indicated. When perfecting the amendment to the specification, applicants should also insert ---, now U.S. Patent No. 6,740,680--- after "May 9, 2002".

As reflected by the attached, completed copies of form PTO-1449 (2 pages), the cited references have been considered.

Claim Objections

Claims 16 and 17 are objected to because of the following informalities:

In claim 16 "is administered" is inappropriate because it represents a method, i.e., dynamic, limitation while the claim is directed to a composition.

In claim 17, line 2 "further" is not appropriate because rather than an additional element being introduced to the composition, the claim is merely further limiting an element already present in the composition, i.e., "the pharmaceutically acceptable carrier".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claims 1 and 4-8, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hellbaum (U.S. Patent No. 3,198,702) who teach pharmaceutical compositions which comprise tetraiodothyroacetic acid (a.k.a. tetrac) as a preferred active agent in admixture with a pharmaceutically acceptable carriers preferably selected from alcohols, most preferably polyhydric alcohols, such a as glycerin, paraffin and water (col. 1, line 65 and col. 2, lines 1-17 and 65-70).

The recitations of the capabilities of the composition in claims 1, 4-8 and 18 are noted, but do not impart patentable moment to the claimed compositions. Applicants' attention is directed to In re Dillon, 16 USPQ2d 1897 at 1900 (CAFC 1990) in which the court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

II Claims 1 and 4-8, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Schibli (GB Patent No. 1,587,638) who teach pharmaceutical compositions suitable or oral administration (page 1, line 38 – page 2, line 4) or administration by injection (a.k.a. parenteral) (page 2, lines 5-7) which comprise tetraiodothyroacetic acid (a.k.a. tetrac) (page 1, lines 34-35) as a preferred active agent (page 1, lines 34-35) in admixture with a pharmaceutically acceptable

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carriers including an alcohol, i.e., propane diol (page 2, lines 15-18), lactose (page 2, lines 23-25), water and lauric acid hexyl ester, i.e., a fatty acid ester (page 4, lines 3-7).

The recitations of the capabilities of the composition in claims 1, 4-8 and 18 are noted, but do not impart patentable moment to the claimed compositions. Applicants' attention is directed to In re Dillon, 16 USPQ2d 1897 at 1900 (CAFC 1990) in which the court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I Claims 1, 2, 4-8 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellbaum (U.S. Patent No. 3,198,702) or Schibli (GB 1,587,638), as above.

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The differences between the above and the claimed subject matter lay in that neither Hellbaum nor Schibli highlight:

- (1) The presence of “an additional thyromimetic compound” (present claim 2); and
- (2) The presently claimed pharmaceutically acceptable carriers (present claim 17).

However, to the skilled artisan, the claimed subject matter would have been obvious because:

(1) Hellbaum (col. 1, lines 45-57) and Schibli (page 1, lines 26-32) teach that not only tetrac, but also other, structurally similar compounds may be present in the compositions and because of the close structural similarity, the Examiner believes that such compounds would also possess the same class of activity, i.e., thyromimetic, as tetrac.

(2) Both Hellbaum and Schibli teach the compositions for pharmaceutical purposes and the addition of other pharmaceutically acceptable carriers than those specifically highlighted in the references would have been readily obvious to the skilled artisan and the artisan would have been motivated to select any specific pharmaceutically acceptable carrier, such as those claimed, in order to facilitate the means of administration which are taught in the references.

II Claims 1-8, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavin et al. (U.S. Patent No. 6,221,911).

Lavin et al. teach pharmaceutical compositions which may comprise at least one thyroid hormone compound or thyroid hormone-like compound, including tetrac and L-thyroxine, as well as pharmaceutically acceptable carriers including an organic solvent such as alcohol and alcohol/water solutions (abstract, col. 5, lines 8-9 and col. 6, line 65 – col. 7, line 4).

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The difference between the above and the claimed subject matter lay in that Lavin et al. fail to highlight each of the presently claimed pharmaceutically acceptable carriers (present claim 17).

However, to the skilled artisan, the claimed subject matter would have been obvious because Lavin et al. teach the compositions for pharmaceutical purposes and the addition of other pharmaceutically acceptable carriers than those specifically highlighted in the reference would have been readily obvious to the skilled artisan and the artisan would have been motivated to select any specific pharmaceutically acceptable carrier, such as those claimed, in order to facilitate the means of administration which are taught in the reference.

It is noted that Lavin et al. limit their compositions to topically applied compositions such as creams, lotions, topical sprays, liposomes, solutions and emulsions (col. 6, lines 17-22), however, it is not seen that the particular pharmaceutical carriers claimed, which represent various classes of hydrophobic and hydrophilic substances, would not be compatible with the topical formulations taught by Lavin et al.

Also, the recitations of the capabilities of the composition in claims 1, 4-8 and 18 are noted, but do not impart patentable moment to the claimed compositions. Applicants' attention is directed to In re Dillon, 16 USPQ2d 1897 at 1900 (CAFC 1990) in which the court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.


None of the claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

October 4, 2004